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**Filed** : September 11, 2003

### **REMARKS**

Claims 1-52 are pending in the present application. Applicants have amended Claims 1, 22 and 42 to replace the phrase “greater than 7% by weight” with “greater than 15% by weight.” As amended, Claims 22 and 42 also specify “said concentrated beta glucan.” Applicants have amended Claim 11 to remove the term “concentrated” and the recitation of the beta glucan concentration. As amended, Claim 11 also now recites “wherein said composition is packaged and labeled as a dietary supplement.” Applicants have amended Claim 32 to recite a composition “prepared by combining a concentrated” beta glucan with a food product. Applicants have amended Claim 49 to replace the term “food product” with the term “pharmaceutically acceptable carrier.”

Applicants maintain that the amendments add no new matter and are fully supported by the specification as originally filed. Support for the amendments to Claims 1, 22 and 42 can be found, for example at paragraph [0023]. Support for the amendment to Claim 11 can be found, for example, in paragraphs [0006], and [0022] through [0024]. Support for the amendments to Claims 32 and 42 can be found, for example in paragraph [0042].

Claims 1-52 are presented for examination. Applicants respond below to the specific rejections raised by the Examiner in the Office Action mailed February 9, 2005.

#### **Rejection Under 35 U.S.C. § 112, second paragraph –Indefiniteness**

The Examiner has rejected Claim 49 as being indefinite for failing to particularly point out and distinctly claimed invention. Specifically, the Examiner maintains that there is no antecedent basis for the phrase “said food product” in Claim 49.

Applicants have amended Claim 49 to replace the phrase “said food product” with the phrase “said pharmaceutically acceptable carrier.” Applicants request that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph accordingly.

#### **Rejection Under 35 U.S.C. § 102(b) – Anticipation**

The Examiner has rejected Claims 1, 3-11, 13-22, 24-32, 34-42, and 44-50 under 35 U.S.C. § 102(b) as allegedly being anticipated by US Patent No. 5,980,918 to Klein (hereinafter “Klein”). According to the Examiner, Klein discloses a composition comprising a glucan having

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a mixed  $\beta(1,3),(1,4)$  linked glucopyranosyl backbone at a concentration greater than 7-10% by weight, thereby anticipating Claim 1. The Examiner asserts that Claims 3-9 are all drawn to the composition of Claim 1. The Examiner argues that neither the process by which the  $\beta$ -glucan is produced nor the source of the  $\beta$ -glucan adds to the patentability of the composition, and therefore concludes that the claims are anticipated by Klein. According to the Examiner, Klein's composition is suitable for oral administration, and therefore maintains that Klein anticipates Claim 10. Further, the Examiner alleges that Claims 11 and 13-19 (drawn to a dietary supplement), as well as Claims 22 and 24-30 (drawn to  $\beta$ -glucan in a cosmetic composition) are all product-by-process claims and do not disclose any ingredient or substance that renders the claimed compositions different from Klein's composition. The Examiner also alleges that the composition disclosed in Klein is in combination with a food product, namely oats, and therefore concludes that Klein anticipates Claims 32, and 34-40. According to the Examiner, Klein discloses a composition comprising  $\beta$ -glucan and a pharmaceutically acceptable carrier, since Klein's composition contains water, which the Examiner maintains is a pharmaceutically acceptable carrier. Thus, the Examiner concludes that Klein anticipates Claims 42 and 44-52. Applicants respectfully traverse.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

As amended, Claims 1, 22 and 42, and Claims 3-10, 24-31 and 44-50 that depend therefrom, recite a beta glucan composition, and a pharmaceutical composition comprising concentrated  $\beta$ -glucan having a concentration "greater than 15% by weight." Klein fails to disclose a beta glucan having a mixed  $\beta(1,3)(1,4)$  linked glucopyranosyl backbone a concentration greater than 15%. Therefore, Klein does not anticipate Claims 1, 3-10, 22, 24-31, 42 or 44-50.

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As amended, Claim 11 and claims 13-21 that depend therefrom recite a composition for reducing low density lipoprotein and total serum cholesterol “wherein said composition is packaged and labeled as a dietary supplement.” Klein does not disclose a composition packaged and labeled as a dietary supplement. Therefore, Klein does not anticipate amended Claims 11 and 13-21.

The Examiner has alleged that Claim 32 and Claims 34-41 are product-by-process claims that are anticipated by Klein’s composition. The Examiner argues that “Klein’s composition is also in combination with a food (oats).” Office Action at 5. Applicants respectfully disagree. While Klein discloses oats as a source of  $\beta$ -glucan, referred to as cereal-derived glucan, or CDG, Klein’s composition uses  $\beta$ -glucan isolated away from the source (Klein, Col. 5, lines 46-49) with other non-food ingredients to create a topical composition for the treatment of wounds and burns. Klein does not describe the combination of the  $\beta$ -glucan derived from oats with any food product. Claim 32 and Claims 34-41 that depend therefrom recite a composition prepared by combining concentrated  $\beta$ -glucan having a mixed  $\beta(1,3)(1,4)$  linked glucopyranosyl backbone with a food product. As discussed above, Klein does not disclose a composition comprising  $\beta$ -glucan that has been combined with a food product, and therefore cannot anticipate Claims 32 and 34-41.

Applicants submit that Klein does not disclose each and every element of amended Claims , 3-11, 13-22, 24-32, 34-42, and 44-50, and therefore Klein is not anticipatory. In view of the above, Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(b).

#### **Rejection Under 35 U.S.C. § 103(a) – Obviousness**

The Examiner has rejected Claims 1-50 as being unpatentably obvious over Klein. In particular, the Examiner asserts that Claim 1 is a product-by-process claim directed to a physiologically concentrated  $\beta$ -glucan having a mixed  $\beta(1,3)(1,4)$  linked glucopyranosyl backbone prepared, having a concentration greater than 7% by weight. According to the Examiner, dependent Claims 2, 12, 33 and 43 are drawn to compositions wherein the concentration of  $\beta$ -glucan is greater than 68% by weight. The Examiner maintains that Klein teaches Applicant’s  $\beta$ -glucan composition, wherein the  $\beta$ -glucan has a concentration of 7-10% by

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weight, that can be used for healing burns and wounds. According to the Examiner, it would have been obvious to one skilled in the art to increase the concentration of  $\beta$ -glucan in Klein's compositions "based on factors like severity of burns, wounds, or scars." Office Action at 7.

Applicants disagree.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art must reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Applicants submit that as Klein lacks any suggestion to modify the composition to increase the concentration of  $\beta$ -glucan, or a reasonable expectation of success in modifying Klein, it cannot support a *prima facie* case of obviousness. The Examiner maintains that "[t]he difference between applicant's claimed composition and the composition of Klein is the concentration. . .of beta glucan." Office Action at 7. Examiner makes the conclusory statement that "[o]ne having ordinary skill in the art would have been motivated , to prepare Klein's beta glucan compositions. . .to be used for healing burns, wounds and scars, based on factors like severity of burns, wounds or scars." *Id.* at 7-8. The Examiner's conclusion presumably rests on the assumption that higher concentrations of  $\beta$ -glucan, the active ingredient in Klein's composition, would be more beneficial in burn or wound healing. However, the Examiner has not pointed to any evidence to suggest that "more is better" regarding the use of  $\beta$ -glucan for the treatment of wounds or burns. Applicants submit that burn and wound healing is a complex and unpredictable cellular process, and that one skilled in the art would not assume that altering the concentration of the active ingredient in Klein's topical composition to include higher concentrations of  $\beta$ -glucan would be beneficial for burn or wound healing. To the contrary, those skilled in the art would appreciate that the relationship between the active ingredient of a composition and its beneficial effects is often not a linear one. Specifically, those skilled in the art would not readily appreciate that higher concentrations of  $\beta$ -glucan would improve wound or burn healing beyond the effects seen with the concentration disclosed. To the contrary, compositions are typically formulated to maximize benefits while minimizing adverse side

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effects. In light of the above, Applicants submit that one skilled in the art would not be motivated to alter the concentration of  $\beta$ -glucan in Klein's composition.

In view of the above, Applicants submit that Klein does not render Claims 1-50 unpatentably obvious. Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 103(a).

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Nevertheless, the Examiner is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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